

## Message Text

UNCLASSIFIED

PAGE 01 STATE 002431

63

ORIGIN HEW-06

INFO OCT-01 OES-05 NEA-09 ARA-10 EA-10 RSC-01 ISO-00 /042 R

66617

DRAFTED BY: DHEW/FDA/JRWEINROTH

APPROVED BY: OES/SCI/BMP:MBEAUBIEN

DHEW/OIH/MACODDING NEA/RA:TGRANT INFO ARA/CAR:TEMACKLIN INFO

ARA/BC/C:AISAACS INFO ARA/CAR:GBHIGH INFO ARA/CEN:JGSULLIVAN INFO

ARA/CEN:PWWACKERBARTH INFO ARA/CEN:DCLARE INFO ARA-LA/CAR:

DCNORTON INFO ARA/CEN:SLIPPE INFO ARA/PAN:RHOWARD INFO

EA/PHL:RTWILLNER INFO

----- 075152

R 062235Z JAN 75

FM SECSTATE WASHDC

TO AMEMBASSY BRIDGETOWN

AMEMBASSY SANTIAGO

AMEMBASSY SAN JOSE

AMEMBASSY SANTO DOMINGO

AMEMBASSY SAN SALVADOR

AMEMBASSY GUATEMALA

AMEMBASSY KINGSTON

AMEMBASSY MANAGUA

AMEMBASSY PANAMA

AMEMBASSY MANILA

AMEMBASSY DOHA

UNCLAS STATE 002431

E.O. 11652: N/A

TAGS: ETRD, TBIO, BB, CI, CS, DR, ES, GT, JM, NU, PN, RP, QA

SUBJECT: RECALL OF DIAGNOSTIC CONTRAST MEDIA

1. FDA ADVISES THAT THE MALLINCKRODT, INC., 2ND AND MALLINCKRODT  
STREETS, ST. LOUIS, MISSOURI 63147 IS RECALLING ALL 50 ML.

VIALS OF THE FOLLOWING PRODUCTS DUE TO THE POSSIBILITY OF NON-  
STERILITY:

1. CONRAY (MEGULMINE IOTHALAMATE INJECTION, U.S.P. 60 PERCENT)  
FOR INTRAVENOUS UROGRAPHY AND ANGIOGRAPHY, LIST NO. 0953,

UNCLASSIFIED

UNCLASSIFIED

PAGE 02 STATE 002431

NDC 19-0953-79 - ALL LOTS WITH THE FOLLOWING EXCEPTIONS:

BLR-E, BPX-B, BRX-A, BRX-B, BRX-D, BRX-E, BSL-A, BSL-B,  
BSL-C, BSL-E, BSR-B, BSR-C, BSR-D, BSR-X, BSR-G.

2. CONRAY 400 (SODIUM IOTHALAMATE INJECTION, U.S.P. 66.8  
PERCENT) FOR INTRAVENOUS UROGRAPHY, INTRAVASCULAR ANGIO-  
CARDIOGRAPHY AND AORTOGRAPHY - LIST NO. 0954 NDC 0954-79 -  
ALL LOTS EXCEPT: BPY-D, BPY-E, BRT-B, BTG-B, BTG-C, BTG-D,  
B TG-E, BTG-G, BTL-A, BTL-B, BTL-D, BTL-E, BTL-G, BTN-C,  
B TN-D, BTN-E, BTN-G.

3. ANGIO CONRAY (SODIUM IOTHALAMATE INJECTION, U.S.P. 80  
PERCENT) FOR INTRAVASCULAR ANGIO-CARDIOGRAPHY AND AORTOGRAPHY,  
LIST NO. 0926 NDC 19-0926-79 - ALL LOTS EXCEPT: BSG-A, BSG-B,  
BSG-C, BSG-D, BSG-E, BSG-G.

4. VASCORAY (MEGULMINE IOTHALAMATE 52 PERCENT (W/V) AND SODIUM  
IOTHALMATE 26 PERCENT (W/V)(LIST NO. C337 NDC 19-C337-79 -  
ALL LOTS EXCEPT: BMA-&, BPP-A, BPP-B, BPP-C, BPP-D, BPP-G.

5. PYELOKON - R BRAND OF SODIUM ACETRIZOATE SOLUTION 20 PERCENT  
FOR RETROGRADE PYELOGRAPHY, LIST NO. 11488 NDC 19-1148-79 -  
ALL LOTS.

6. CYSTO-CONRAY (MEGULMINE IOTHALAMATE 43 PERCENT (W/V) FOR  
RETROGRADE CYSTOGRAPHY, CYSTO-URETHROGRAPHY, AND RETROGRADE  
PYELOGRAPHY, LIST NO. 7649 NDC 19-7649-79 - ALL LOTS.

2. FOREIGN CONSIGNEES, AS FOLLOWS:

BOOKERS AGENCIES BARBADOS LTD., P.O. BOX 139, BRIDGETOWN,  
FONTABELLE, ST. MICHAEL, BARBADOS

UNIVERSIDAD CATOLICA DE CHILE, CASILLA 114-D, SANTIAGO, CHILE

UDISCA LTDA, APARTADO 729, SAN JOSE, COSTA RICA

HOSPITAL NACTIONAL DE NINOS, APARTADO 1654, SAN JOSE, COSTA  
RICA

CAJA COSTARRICENSE DE SEGURO SOCIAL, DEPARTAMENTO DE  
UNCLASSIFIED

UNCLASSIFIED

PAGE 03 STATE 002431

APROVISIONAMIENTO, APARTADO 10105, SAN JOSE, COSTA RICA

LABORATORIOS ROLDAN CPCRA, KM 5 1/2 CARR. SANCHEZ, SANTO  
DOMINGO, DOMINICAN REPUBLIC

HOSPITAL ROSALES, C/O DR. RUBEN CARDANO, SAN SALVADOR, EL  
SALVADOR, CENTRAL AMERICA

REPRESENTACIONES ROBERTO MONGE, LO AVENIDA 11-50 ZONA 15  
VISTA HERMOSA 111, GUATEMALA CITY, GUATEMALA

UNIVERSITY OF THE WEST INDIES, MONA KINGSTON 7, JAMAICA W.I.

FACEY COMMODITY CO. LTD. 158-160 HARBOUR ST, KINGST  
N, JAMAICA

SUPLIDCKA INTERNATIONAL SA, DEL CINE MASAYA 75 VARAS ABAJO,  
APARTADO POSTAL NO. 60, MASAYA, NICARAGUA

F. ICAZA AND CO., INC., P.O. BOX 2140 AVE JUSTO ARCSERENA,  
NO. 25 - 45 PANAMA 1, PANAMA

MARSMAN & CO. INC., P.O. BOX 297, MANILA, PHILIPPINES

EBN SINA PHARMACY, P.O. BOX 337, DOHA QATAR ARABIAN GULF

3. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES TO DETERMINE  
IF THE FIRMS ARE FAMILIAR WITH THE DETAILS OF THE RECALL. IN  
ADDITION, POST MAY WISH TO INFORM HOST GOVERNMENT DRUG CONTROL  
AUTHORITIES OF DETAILS OF THE RECALL. KISSINGER

UNCLASSIFIED

NNN

## Message Attributes

**Automatic Decaptioning:** X  
**Capture Date:** 01 JAN 1994  
**Channel Indicators:** n/a  
**Current Classification:** UNCLASSIFIED  
**Concepts:** DRUG INDUSTRY, RECALLS  
**Control Number:** n/a  
**Copy:** SINGLE  
**Draft Date:** 06 JAN 1975  
**Decaption Date:** 01 JAN 1960  
**Decaption Note:**  
**Disposition Action:** n/a  
**Disposition Approved on Date:**  
**Disposition Authority:** n/a  
**Disposition Case Number:** n/a  
**Disposition Comment:**  
**Disposition Date:** 01 JAN 1960  
**Disposition Event:**  
**Disposition History:** n/a  
**Disposition Reason:**  
**Disposition Remarks:**  
**Document Number:** 1975STATE002431  
**Document Source:** CORE  
**Document Unique ID:** 00  
**Drafter:** DHEW/FDA/JRWEINROTH  
**Enclosure:** n/a  
**Executive Order:** N/A  
**Errors:** N/A  
**Film Number:** D750005-0922  
**From:** STATE  
**Handling Restrictions:** n/a  
**Image Path:**  
**ISecure:** 1  
**Legacy Key:** link1975/newtext/t19750175/aaaacnuu.tel  
**Line Count:** 137  
**Locator:** TEXT ON-LINE, ON MICROFILM  
**Office:** ORIGIN HEW  
**Original Classification:** UNCLASSIFIED  
**Original Handling Restrictions:** n/a  
**Original Previous Classification:** n/a  
**Original Previous Handling Restrictions:** n/a  
**Page Count:** 3  
**Previous Channel Indicators:** n/a  
**Previous Classification:** n/a  
**Previous Handling Restrictions:** n/a  
**Reference:** n/a  
**Review Action:** RELEASED, APPROVED  
**Review Authority:** ShawDG  
**Review Comment:** n/a  
**Review Content Flags:**  
**Review Date:** 24 FEB 2003  
**Review Event:**  
**Review Exemptions:** n/a  
**Review History:** RELEASED <24 FEB 2003 by RicharJA>; APPROVED <12 FEB 2004 by ShawDG>  
**Review Markings:**

Margaret P. Grafeld  
Declassified/Released  
US Department of State  
EO Systematic Review  
05 JUL 2006

**Review Media Identifier:**  
**Review Referrals:** n/a  
**Review Release Date:** n/a  
**Review Release Event:** n/a  
**Review Transfer Date:**  
**Review Withdrawn Fields:** n/a  
**Secure:** OPEN  
**Status:** NATIVE  
**Subject:** RECALL OF DIAGNOSTIC CONTRAST MEDIA  
**TAGS:** ETRD, TBIO, BB, CI, CS, DR, ES, GT, JM, NU, PN, RP, QA, US, MALLINCKRODT INC  
**To:** BRIDGETOWN MULTIPLE  
**Type:** TE  
**Markings:** Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 05 JUL 2006